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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/799,143

03/11/2004

Lutz Biedermann

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EXAMINER

HOFFMAN, MARY C

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

11/12/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/799,143	Applicant(s) BIEDERMANN ET AL.	
	Examiner MARY HOFFMAN	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-15,21,22 and 25-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-15,21,22 and 25-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/8/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

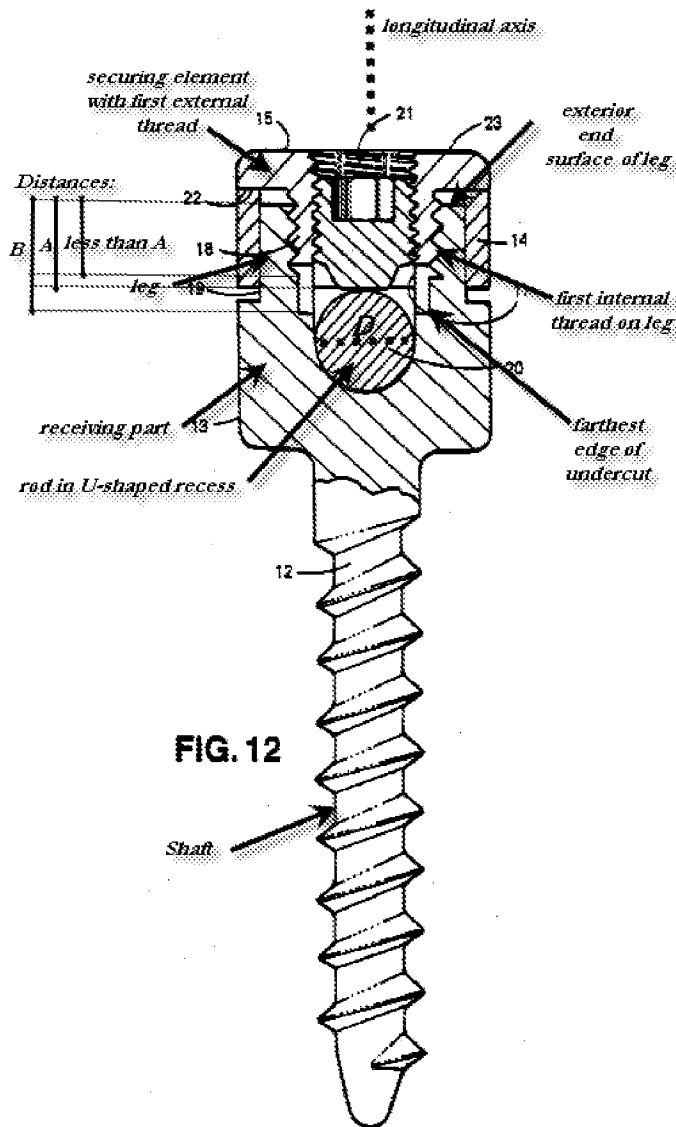
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7-8, 21, 27, 29-30, 35-36, and 39-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Mehdiian (U.S. Patent No 5,217,497).

Mehdiian discloses an anchoring element (See marked up figure below) for use in spinal or bone surgery; the anchoring element comprising: a shaft for anchoring in a vertebra or a bone section; a rod having a pre-determined diameter (D) and an outer surface; a receiving part, which is connected to the shaft and is structured and arranged to connect to the rod, the receiving part having a longitudinal axis and comprising a U-shaped recess forming a channel for the reception of the rod and two legs having free ends, the legs comprising a first internal thread, the legs further providing an exterior end surface of the receiving part; and a securing element comprising a screw member having a first external thread that engages and cooperates with the first internal thread; whereby a first distance from the exterior end surface of the receiving part to a closest portion of the outer surface of the rod in an axial direction is a pre-determined distance (A); the first internal thread extending from the exterior end surface of the receiving part to a second distance that is smaller than or equal to the pre-determined distance (A);

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and the receiving part further comprising an undercut (*i.e.* a cut made in a lower part: a cut made below another cut or into the lower part of something- see Encarta® World English Dictionary, North American Edition online for definition) extending circumferentially and the first internal thread extending to the undercut, the undercut having an edge farthest away from the first internal thread, the edge being located at a third distance (B) from the exterior end surface, the distance (B) being larger than the predetermined distance (A). A connection between the shaft and the receiving part is structured and arranged to be a monoaxial connection. The shaft and the receiving part are an integral part. The first thread comprises fewer than four full turns.



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehdiian (U.S. Patent No 5,217,497) in view of Harms et al. (U.S. Patent No. 5,873,878).

Mehdiian discloses the claimed invention except for the screw nut having an internal thread; and wherein the receiving part further comprises an external thread that cooperates with the internal thread of the screw nut.

Harms et al. disclose a screw nut (ref. #12) having an internal thread; and wherein the receiving part further comprises an external thread that cooperates with the internal thread of the screw nut for fixation of the rod in combination with an internal screw.

It would have been obvious to one skill in the art at the time of the invention was made to make an device of Mehdiian by substituting the screw nut having an internal thread and the receiving part with an external thread in view of Harms et al. for the collar in order to achieve fixation of the rod in combination with an internal screw and to reduce splaying of the arms.

Claims 6 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehdiian (U.S. Patent No 5,217,497) in view of Hall (U.S. Patent No. 4,041,939).

Mehdiian discloses the claimed invention except for the threads being selected from a metric thread, a buttress thread, a flat thread or a thread with a negative load-bearing angle.

Hall discloses of using anchoring elements with buttress threads, which allows the element to be firmly secured (col. 1, lines 51-60).

It would have been obvious to one skill in the art at the time of the invention was made to make an device of Mehdian with buttress threads in view of Hall in order to have a firmly secured anchor element. Moreover, it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the threads of Mehdian being selected from a metric thread, a buttress thread, a flat thread or a thread with a negative load-bearing angle, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing threads. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

Claims 33-34 and 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehdian (U.S. Patent No 5,217,497) in view of Jackson (U.S. Patent No. 6,224,596).

Mehdian discloses the claimed invention except for the securing device being flush with the receiving part.

Jackson discloses a securing device being flush with the receiving part (FIG. 7) as another example of a securing device in a polyaxial screw capable of securing a rid to the screw.

It would have been obvious to one skill in the art at the time of the invention was made to make an device of Mehdian with a securing device being flush with the

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receiving part in view of Jackson, since such a securing device is a functional equivalent and would provide the predictable result of securing the rod to the screw.

Claims 2, 22 and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehdian (U.S. Patent No 5,217,497) in view of German Patent DE29810798.

Mehdian discloses the claimed invention except for the undercut having a depth that corresponds at least to the depth of the thread, and there being no thread runout at an end of the first thread opposite to the exterior end surface because the undercut is at least equal to a depth of the first thread.

DE29810798 discloses an undercut having a depth that corresponds at least to the depth of the thread, and there being no thread runout at an end of the first thread opposite to the exterior end surface because the undercut is at least equal to a depth of the first thread (See FIGS. 1-2) as a suitable termination structure for machined threads in a bone screw/rod system.

It would have been obvious to one skill in the art at the time of the invention was made to make an device of Mehdian with the undercut having a depth that corresponds at least to the depth of the thread, and there being no thread runout at an end of the first thread opposite to the exterior end surface because the undercut is at least equal to a depth of the first thread in view of DE29810798 since it has been discloses as a suitable termination structure for machined threads in a bone screw/rod system and would have provided the predictable result of allowing the set screw to be fixed to the receiver.

Response to Arguments

Applicant's arguments filed 06/08/2009 have been fully considered but they are not persuasive.

Applicant argues that Mehdian lacks an undercut. The term "undercut" does not necessarily require an overhanging part. According to Encarta® World English Dictionary, North American Edition online, an undercut is a cut made in a lower part: a cut made below another cut or into the lower part of something. The hollowed out portion beneath the threaded region of the Mehdian reference meets this definition. The hollowed out part extends circumferentially.

The rejections are deemed proper.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARY HOFFMAN whose telephone number is (571)272-5566. The examiner can normally be reached on Monday-Thursday 10:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary C. Hoffman/
Examiner, Art Unit 3733
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733